



August 15, 2001

Food and Drug Administration

466 Fernandez Juncos Avenue

Puerta De Tierra

San Juan, Puerto Rico 00901-3223

**WARNING LETTER**

**SJN-01-16**

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Mr. Peter J. Cano  
President  
Asian American Trading Co., Inc.  
Avenida Piñero 1627 Caparra Terrace  
San Juan Puerto Rico, 00920

Dear Mr. Cano:

On May 1, 8, & 11, 2001, the Food and Drug Administration (FDA) conducted an inspection of your facility located at Avenida Piñero 1627 Caparra Terrace, San Juan Puerto Rico, 00920. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 CFR 123).

During our inspection, the FDA investigator observed that the HACCP plan for the imported products failed to address histamine and Ciguatera controls, two significant hazards. The FDA investigator also provided you with a copy of the Import Seafood HACCP Report (form FDA 3502), which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

HACCP plan for scombroid fish species processed by [REDACTED] failed to address histamine controls which is a significant hazard; and the HACCP plan for gutted red snapper processed by [REDACTED] failed to address Ciguatera fish poison (CFP) as a significant hazard.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates


Mr. Peter J. Cano  
August 15, 2001  
Page 2

for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed with 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Carlos I. Medina, Compliance Officer, 466 Fernandez Juncos Avenue, San Juan, Puerto Rico, 00901. If you have questions regarding any issue in this letter, please contact the above person at 787-729-6894 extension 2110. You may also contact Jaime Pares, CSO at 729-6894 extension 2106 for answers and/or direction towards guidance and sources of training to achieve compliance.

Sincerely,

  
Mildred R. Barber  
District Director